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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/780,954 | 02/18/2004 | Rizzo Rosario | 71297 | 2345 |

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EXAMINER

AMARELD JR, ROBERT W

ART UNIT PAPER NUMBER

3738

DATE MAILED: 01/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|----------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/780,954 | ROSARIO, RIZZO | |
| | Examiner | Art Unit | |
| | Robert W. Amareld, Jr. | 3738 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 February 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the **tang of claim 5** must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "**means**" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," "**The invention refers to,**" etc.

Furthermore, the title of the document should not be above the "abstract" heading.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Day (US Pat# 5895396). Day discloses pin (interpreted as a micro-nail) (1), having a head (2), for use in bone of the jaw for oral surgery (column 3, lines 20-37) for the retention of a membrane (6) to the bone. Figure 3 shows the pin fitted into a bony structure (8) with at least one retaining structure (2), where the membrane (6) is shown to be fastened to the nail by the retaining member (2).

Claims 2-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Pelo (US Pub# 2003/0032961, Appl# 10/195719). Pelo discloses a nail (Figures 1,5,6,19) comprising a shank and head with a means of retention directly, with the pointed end (16) and annular grooves, or retention with a bone plug/cap/ring (170, Figure 19) as a retention element or in the embodiment in Figure 6, the nut (44) may be the retention element. The pointed head (16) is fully capable of engaging a membrane as is the threaded head embodiment (42) where the retention element (44 or 170), depending on the embodiment) is capable of encircling the head and super imposing on the membrane. The embodiment in Figure 5 & 19, clearly has an annular groove at the base of the head (16) that is fully capable of holding a membrane where the head (16) is capable of perforating it. The head portion (16) may be interpreted as a 'tang' that may be folded if the device is made from flexible extracellular matrix (ECM) material (Page 8, column 1 lines 7-9) or polymer material (Paragraph 0102) where a retention bone plug (170) may be compressed over the structure, enclosing a membrane that is capable of being attached to the device. The pointed head (16) is interpreted as a press stud, which is capable of being a means for perforating a membrane and guiding it to the annular groove at the base, where the head (16) is connected by thinner portion, which is weaker because it is thinner and is capable of being removed (separable) by clipping or breaking it away. The bone plug (170) is fully capable of being a retention ring. The device contains a supporting flange (12) where the annular groove is between the flange and the head (16) where the head perforation portion (16) is tapered and

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joined to the head (12) through a weakened thin portion, which makes up the groove, which is weaker because it is structurally thinner and capable of being a breakage part.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Pham, US Pat# 6197030-retractable pin; Spetzler, US Pat# 5954726-cranial pin; Anspach, US Pat# 5501695-fastener; Grundei, US Pat# 4629463-conection of bones; Tormalaet, US Pat# 6692499-fastener for tissue; Bowman, US Pat# 6402766-fixation device; Goble, US Pat# 5013316-anchor system; Le, US Pat# 5545180-anchor; Worcel, US Pat# 5437674-osteosynthesis device.

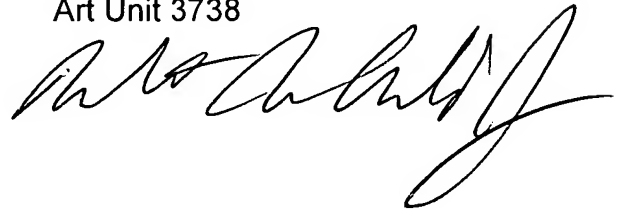
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert W. Amareld, Jr. whose telephone number is 571-272-6170. The examiner can normally be reached on M-F 9am -5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert W Amareld, Jr.
Examiner
Art Unit 3738



RWA

BRIAN E. PELLEGRINO
PRIMARY EXAMINER

